



SPC Proposal Number	
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## RESEARCH STUDY UPDATE

### I. Study Information

Title of approved research:	
Date of initial approval:	
Purpose of this update (check one)	<input type="checkbox"/> Annual Report – Study Renewal Request <input type="checkbox"/> Final Report – Study Closure Request <input type="checkbox"/> Amendment – Study Change Request

### II. Primary Investigator & SPC Sponsor Information

Primary Investigator	
Name	
Phone Number	
E-mail	
SPC Affiliation	<input type="checkbox"/> Full Time Faculty <input type="checkbox"/> Adjunct / Part-time Faculty <input type="checkbox"/> Non-faculty employee <input type="checkbox"/> Student <input type="checkbox"/> None

SPC Sponsor	
Name	
Phone Number	
E-mail	
SPC Affiliation	<input type="checkbox"/> Full Time Faculty <input type="checkbox"/> Non-faculty employee

### III. Update Purpose

<p>Check the reason(s) for the requested update</p>	<p><b>Renewal</b></p> <p><input type="checkbox"/> Enrollment not started</p> <p><input type="checkbox"/> Enrollment still in progress</p> <p><input type="checkbox"/> Enrollment complete but data still being collected</p> <p><input type="checkbox"/> Data collection complete but data analysis still in progress</p> <p><input type="checkbox"/> Other (explain below)</p> <p><b>Closure</b></p> <p><input type="checkbox"/> Study finished and complete including paper and/or presentation submissions</p> <p><input type="checkbox"/> Study started but discontinued before completion</p> <p><input type="checkbox"/> Study never started</p> <p><input type="checkbox"/> Other (explain below)</p> <p><b>Amendment</b></p> <p><input type="checkbox"/> Change in personnel</p> <p><input type="checkbox"/> Change in protocol (including increases in number of subjects)</p> <p>Explain change briefly below and attach a detailed description of the requested change(s) to this form.</p>
<p>Explain briefly the reason for the request.</p>	

### IV. Study Administration

1. If an informed consent was required, did all participants sign the consent?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> n/a
2. Are all signed consents on file?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> n/a
3. Have there been any adverse effects on participants or non-participants related to this research?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> n/a
4. Have there been any complaints about this study from participants or non-participants?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> n/a
5. Has any new information in your field arisen that might affect subjects' willingness to participate?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> n/a
6. Have there been any changes in the risks and/or benefits to subjects since the last approval.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> n/a
7. Have there been any breaches of confidentiality?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> n/a
8. Has there been action taken by another IRB since the last SPC approval or review of the research?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> n/a
9. Have there been any changes in the research team (Researcher or Sponsor)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> n/a
10. Have there been any internal or external audits, financial or scientific, of the study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> n/a
Please explain any answers of "yes" to the above questions here:			

## V. Study Summary

*Please answer the questions below for the study as of the date of this update. All questions require a response regardless of the reason for the update.*

1. Provide a summary of the research progress to date. If you have not yet enrolled subjects, please explain why. If you are closing your study application, explain what you will do with identifiable data and/or the link to the subjects' identities.

2. How many subjects have been enrolled in the study to date? If there are none, state "None".

3. Describe any unanticipated problems that may be related to the research that have occurred since the last approval. If there are none, state "None".

4. Provide an abstract of the research results to date in plain language. At a minimum include the Purpose, Methods, Results and Conclusions sections. If there are none, state "None".

**V. Researcher and Sponsors Assurances:**

- I, the undersigned, acknowledge that this research is governed by the Board of Trustees Rules and the College Procedures of St. Petersburg College, as well as state and federal law concerning educational research, privacy and confidentiality.
- I hereby agree to follow all guidelines and regulations of this institution and will maintain the confidential nature of records and the privacy rights of all participants.
- If this is a request for renewal or amendment, I agree to continue to abide by all of the guidelines outlined in the original application unless they are specifically changed in writing.
- By my signature I agree that this study will be/has been conducted according to the proposal as submitted to the Research Review Committee.

\_\_\_\_\_

Primary Researcher's signature

\_\_\_\_\_

Date

\_\_\_\_\_

Sponsor's signature

\_\_\_\_\_

Date

## Required Materials

To avoid undue delay in the processing of this update, investigators are asked to review this document carefully to make sure all of the required components are present. The following documents are required for the named update type:

### Renewal Requests

- Completed and signed “Research Study Update” form
- Determinations (approvals or disapprovals) from any other IRBs or Review boards for this proposal since the last review
- If a change to personnel or the proposal is also requested, include information as listed below

### Study Closures Requests

- Completed and signed “Research Study Update” form
- Copies of all manuscripts and presentations resulting from the study

### Proposal Amendment Requests

- Completed and signed “Research Study Update” form
- Copy of the full Research Proposal with requested amendments highlighted
- Copies of any study materials (data collection materials, tools, scripts, recruitment materials, consent forms, etc.) for which changes are requested
- Copies of any other materials pertinent to the change (i.e. funding letter, etc.)

### Personnel Amendment Requests

- Completed and signed “Research Study Update” form
- Detailed information on which personnel are to be deleted and which added including complete contact information for new personnel
- Proof of humans subjects trained for all new personnel
- Signed Assurances (as applicable) for all new personnel

Please forward these materials by e-mail or postal mail to:

E-mail: [Research\\_Review@spcollege.edu](mailto:Research_Review@spcollege.edu)

Mail: St. Petersburg College  
Department Institutional Research  
Epicenter  
P.O. Box 13489  
St. Petersburg, FL 33733

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